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INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

GUIDELINES FOR AN IMPORT REGULATORY SYSTEM



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INTRODUCTION

Scope	3
References	3
Definitions, abbreviations and acronyms	3
Outline of requirements	5

GENERAL REQUIREMENTS

1. Purpose, approach and coverage	7
1.1 Regulated articles	7
1.2 Regulated pests	7
1.3 Phytosanitary measures	7
2. Factors determining the nature of import regulations	8
2.1 International obligations	8
2.2 Requirements of regional organizations	8
2.3 National organizations	9
2.4 NPPO obligations	9
2.5 Requirements of national stakeholders	9
3. Relationship to international agreements principles, and standards	10
3.1 Factors affecting the construction of regulations	10
3.1.1 Sovereignty	10
3.1.2 Necessity and justification	10
3.1.3 Non-discrimination	10
3.1.4 Minimal impact	10
3.1.5 Harmonization	10
3.1.6 Scientific basis for measures and the role of pest risk analysis	10
3.1.6.1 Consistency	11
3.1.7 Managed risk	11
3.2 Factors affecting the application of regulations	11
3.2.1 Modification	11
3.2.2 Emergency action and provisional measures	11
3.2.3 Provision of information	12
3.2.3.1 Official contact point	12
3.3 Operational activities arising from regulations	12
3.3.1 Categorizing and listing pests	12
3.3.2 Provision for special imports	12
3.3.3 Designation of pest free areas, areas of low pest prevalence, and official control programmes	12
3.3.4 Recognition of equivalence	12
3.3.5 Provision of rationale	13
3.3.6 Dispute settlement	13
3.3.7 Inspection	13
3.3.8 Treatment	13
3.3.9 Non-compliance reporting	13
4. Components of an import regulatory system	13
4.1 Legal authority	13
4.1.1 Management responsibility	14

4.2	Procedures of an import regulatory system	15
4.2.1	Regulation construction	15
4.2.1.1	Technical evaluation	15
4.2.1.2	Import authorization	15
4.2.2	Dispute resolution	16
4.2.3	Dissemination of regulatory information	16
4.2.4	Checking compliance with regulations	16
4.2.4.1	Phytosanitary documentation	17
4.2.4.2	Inspection and testing	17
4.2.4.3	Audit of production procedures	17
4.2.4.4	Supporting administrative procedures	17
4.2.5	Response to non-compliance	18
4.2.5.1	Non-compliance measures	18
4.2.5.2	Notification of non-compliance	18
4.3	Resources	18
4.3.1	Staff	18
4.3.2	Information on pests	18
4.3.2.1	Non-regulated pests within the importing country	18
4.3.2.2	Regulated pests	19
4.3.3	Technical information provided to NPPO personnel	19
4.4	Equipment	19
4.5	Documentation	19
4.5.1	Procedures	19
4.5.2	Records	20
4.6	Communication	20
4.7	Review mechanism	20
4.7.1	System review	20
4.7.2	Incident review	20
4.8	Agency linkages	20

GUIDELINES FOR AN IMPORT REGULATORY SYSTEM

INTRODUCTION

Scope

This standard describes the factors that need to be taken into account when developing and/or revising an import regulatory system and the components of such a system. An import regulatory system represents the extension of authority provided in enabling legislation to prescribe and adopt regulations, and to implement phytosanitary procedures with the aim of preventing the entry and establishment of regulated pests of plants, plant products and other regulated articles.

References

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Glossary of phytosanitary terms, 1997. ISPM Pub. No. 5, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM Pub. No. 2, FAO, Rome.
Inspection methodology, FAO, Rome (in draft).
International Plant Protection Convention, 1997. FAO, Rome.
Principles of plant quarantine as related to international trade, 1995. ISPM Pub. No. 1, FAO, Rome.
Requirements for the establishment of pest free areas, 1996. ISPM Pub. No. 4, FAO, Rome.

Definitions, Abbreviations and Acronyms

(*) indicates terms/definitions not included in the Glossary of Phytosanitary Terms (1999) or not appearing as indicated in this listing.

Compliance*	In accordance with stated requirements or known obligations
Consignment*	A quantity of plants, plant products and/or other regulated articles being moved from one country to another and covered when required by a single phytosanitary certificate (a consignment may be composed of one or more lots)
Detention	Keeping a consignment in official custody or confinement for phytosanitary reasons
Emergency action*	A phytosanitary action undertaken in the face of a new and/or unexpected phytosanitary situation. Emergency action may or may not be associated with, or followed by, the establishment of emergency measures
Inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations

Inspector	Person authorized by a National Plant Protection Organization to discharge its functions
Interception (of a consignment)	The refusal or controlled entry of an imported consignment due to failure to comply with phytosanitary regulations
Introduction	The entry of a pest resulting in its establishment
IPPC	Acronym for the International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended
NPPO	Acronym for National Plant Protection Organization
Official	Established, authorized or performed by a National Plant Protection Organization
Pathway	Any means that allows the entry or spread of a pest
Pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products
Pest free area (PFA)	An area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained
Pest risk analysis (PRA)	Pest risk assessment and pest risk management
Phytosanitary certificate	Certificate patterned after the model certificates of the IPPC
Phytosanitary legislation	Basic laws granting legal authority to a National Plant Protection Organization from which phytosanitary regulations may be drafted
Phytosanitary measure	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of pests
Phytosanitary procedure*	Any officially prescribed method for developing or implementing phytosanitary regulations including the performance of inspections, tests, surveys or treatments in connection with regulated pests
Phytosanitary regulation*	Official rule to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests, including establishment of procedures for phytosanitary certification
Plant products	Unmanufactured material of plant origin (including grain) and those manufactured products that, by their nature or that of their processing, may create a risk for the introduction and spread of pests
Plants	Living plants and parts thereof, including seeds and germplasm

Quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled
Region	The combined territories of the member countries of a Regional Plant Protection Organization
Regional plant protection organization (RPPO)	Intergovernmental organization with the functions laid down by Article IX of the IPPC
Regulated article	Any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved
Regulated pest	A quarantine pest or a regulated non-quarantine pest
Spread	Expansion of the geographical distribution of a pest within an area
Treatment	Officially authorized procedure for the killing, removal or rendering infertile of pests

Outline of Requirements

This standard describes the purpose and components of an import regulatory system.

The objective of the import regulatory system is to prescribe and implement phytosanitary measures to prevent the entry and/or establishment of regulated pests when it has been determined that regulations are necessary for the proper management of pest risks associated with imported pests, plants, plant products, or other articles deemed to require phytosanitary measures. Phytosanitary measures include the legislation, regulations, and phytosanitary procedures that deal with the import of plants, plant products, and other regulated articles.

The strength of an import regulatory system is its scientific approach. To achieve the maximum effectiveness in the prevention of the introduction of regulated pests by the use of phytosanitary measures, an import regulatory system should utilize pest risk analysis as the basis for formulating regulations. This involves the following elements:

- identification, characterization, and categorization of regulated pests and the pathways for their movement;
- assessment of the pest risk associated with the pests and pathways;
- management of the pest risk, including the identification of risk management options;
- selection of management options taking into account,
 - efficacy in risk mitigation
 - relevant international and national obligations
 - operational and administrative feasibility of different options and their impacts.

The IPPC (1997) describes in detail the obligations of contracting parties and their NPPOs in regard to the formulation of import regulations. As the role of the IPPC has been substantially clarified with respect to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (the WTO-SPS Agreement), a number of these requirements are also noted in relation to the latter agreement. Likewise, there is noted overlap with the principles identified in *Principles of plant quarantine as related to international trade* (ISPM No. 1).

Further factors influencing an import regulatory system, from regional to those involving national export and import industries, are described in general terms only, as they will be different for different countries.

NPPOs need to ensure that governments, growers, industry groups and their representatives, understand the range of their responsibilities and obligations, and the limitations as well as the benefits arising from international and national agreements. These responsibilities and obligations can be outlined in national standards within a country or in documents describing the national import regulations and the associated administrative structure.

Note: As additional ISPMs are drafted and adopted, the phytosanitary responsibilities of NPPOs will be more closely defined and described. For example, the ISPM *Guidelines for pest risk analysis* provide additional guidelines for NPPOs. Further guidelines on the use of pest risk analysis are planned.

GENERAL REQUIREMENTS

1. Purpose, approach, and coverage

The purpose of an import regulatory system is to provide an operational means for extending the authority provided in enabling legislation to official systems managing regulated articles, regulated pests and the application of phytosanitary measures to achieve the level of plant protection which is deemed necessary and can be justified by the importing contracting party.

1.1 Regulated articles

Regulated articles are defined as “any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved”. Regulated articles include a wide range of items that may be infested, contaminated or associated with regulated pests. Following are examples of articles that are typically regulated:

- plants and plant products such as those used for:
 - propagation,
 - consumption,
 - processing,
 - any other purpose;
- conveyances and transportation facilities;
- packing material;
- storage facilities;
- traveller’s personal effects moving internationally;
- soil and related material;
- pests and biological control agents;
- research and other scientific material.

1.2 Regulated pests

Regulated pests can be either quarantine pests or regulated non-quarantine pests. The criteria for categorizing these pests must be clear. Pests that have been so categorized should be identified in pest lists so that the NPPO of an exporting country can be aware of the pests for which measures are required and apply the appropriate procedures (e.g. use of tolerances for non-quarantine pests) prior to export. Pests previously unknown to the importing contracting party or pests that cannot be identified to the level needed to confirm whether they are regulated pests, may be categorized as regulated pests on an emergency or provisional basis where the NPPO has reason to believe that such pests pose a potential phytosanitary threat. (see also ISPM No. ?)

1.3 Phytosanitary measures

Phytosanitary measures are used to prevent or impede the movement of regulated pests. These may include:

- regulations that:
 - require compliance with conditions or place restrictions (e.g. on movement, usage),
 - prohibit entry, remove, or destroy;
- procedures concerning:

- inspection and/or testing,
- treatment,
- emergency actions;
- operational phytosanitary activities undertaken by an NPPO either:
 - at the point of import,
 - at a designated point following import,
 - at the area of origin/export,
 - some combination of the above.

Selection of the appropriate risk management options and resultant regulatory conditions for the control of all regulated articles involves the balancing of technical recommendations and many other factors that impact on regulatory decision-making.

2. Factors determining the nature of import regulations

NPPOs must recognize and take account of all the factors that impose requirements on the nature of import regulations. These factors may include:

- international obligations imposed by international treaties, conventions, or similar agreements;
- regional obligations imposed by regional treaties, conventions, or similar agreements;
- nationally binding rules or obligations of the government of the contracting party;
- organizational obligations, such as laws and policies of the government ministry or department or NPPO; and
- requirements of national stakeholders.

2.1 International obligations

National governments have the sovereign right to regulate imports according to their needs and taking into account their international obligations. The IPPC makes provision for contracting parties concerning their international responsibilities, obligations, and powers for making regulations for the protection of plants and plant products from the introduction and spread of pests. The IPPC and the WTO-SPS Agreement are closely related in this respect. Other international agreements may also be pertinent to aspects of regulating for plant protection and/or trade.

NPPOs should be aware of the various obligations of their government under international agreements and strive to ensure that national regulatory systems are appropriately designed and implemented in recognition of relevant obligations.

2.2 Requirements of regional organizations

Regional organizations, such as Regional Plant Protection Organizations (RPPOs), regional economic integration organizations or regional agricultural development organizations, may also have requirements which impinge on import regulatory systems.

RPPOs may have particular requirements, (e.g., reporting non-compliance with regulations), which the member governments of the RPPO have agreed to observe. A regional economic integration organization may have rules that apply to all members and may also have the authority to enact and enforce certain regulations on behalf of all member states. NPPOs affected by such requirements should take them into account when developing and implementing

their import regulations.

2.3 National obligations

It is recognized that NPPOs are bound to observe their governments' legal and administrative processes in the development and establishment of import regulations. Legal and administrative instruments and government policies will in large part determine the format and structure of, and procedures for, import regulatory systems. Thus, despite a desire for international conformity in phytosanitary regulations, it is clear that a degree of flexibility is necessary to accommodate such diversity.

To some extent, these considerations will also influence the content of import regulations. The particular concerns of government policies are likely to lend emphasis to certain regulations. In any case, regulations should follow the general guidelines provided in relevant international treaties, agreements, and standards.

Governments also determine the priority and level of authority given to import regulations and the resources provided to the NPPO for implementation. These factors are important considerations for distinguishing the level of protection that may be desired and what is practical to achieve.

2.4 NPPO obligations

In constructing their import regulatory system, NPPOs should take into account the organizational requirements of their Ministry (or equivalent) and the NPPO itself. These may include requirements concerning the:

- setting of organizational level policy in strategy or policy statements, or the general standards of the NPPO;
- establishment of administrative procedures for administering the operations and particular requirements of the NPPO;
- development and adoption of sets of regulations describing the import requirements of the NPPO;
- evaluation of pest risks;
- setting of regulatory priorities.

2.5 Requirements of national stakeholders

Apart from the legal, administrative and policy requirements that define the nature of import regulations, the requirements of sister agencies in the national government and domestic stakeholders such as the export and import industries of a contracting party may have a significant effect on import regulations. Consultation and collaboration with relevant agencies as well as affected industries and concerned private sector groups is important for increasing the understanding and acceptance of regulatory decisions by the private sector and is often useful for the improvement of regulations by the NPPO.

3. Consideration of international agreements, principles and standards

Obligations associated with international agreements as well as the principles and standards following from international agreements, in particular the IPPC and the WTO-SPS Agreement, have a significant effect on the structure of import regulatory systems. These include effects on the construction of import regulations, the application of regulations, and the operational activities arising from regulations.

3.1 Factors affecting the construction of regulations

The construction of regulations requires consideration of the principles of sovereignty, necessity, non-discrimination, minimal impact, and harmonization. The scientific basis for phytosanitary measures and the principle of managed risk are also key factors to consider in the construction of regulations.

3.1.1 Sovereignty

Contracting parties should recognize the authority of other contracting parties in describing and implementing phytosanitary measures. The powers of contracting parties under the IPPC are listed in Article VII, paragraph 1, and include powers to make regulations, prohibit, detain, inspect, restrict movement, and require treatment or destruction. Contracting parties should apply this authority through an NPPO.

3.1.2 Necessity and justification

Contracting parties should only apply phytosanitary measures where necessary for phytosanitary purposes and where such measures are technically justified. Technically justified measures are based on pest risk analysis or where applicable, another comparable examination and evaluation using scientific principles and evidence.

3.1.3 Non-discrimination

The principle of non-discrimination is fundamental to fair trade. When applied to phytosanitary measures it states that there should not be any discrimination between contracting parties where the same conditions exist, and there should not be unjustified discrimination between domestic and imported consignments in the case of quarantine pests under official control or regulated non-quarantine pests.

3.1.4 Minimal impact

In constructing regulations, contracting parties should ensure that import regulations are the least intrusive and cause minimum interference with international trade as is consistent with their effectiveness and taking into account technical and economic feasibility.

3.1.5 Harmonization

Harmonization is the process of establishing national phytosanitary measures consistent with international standards where they are available. Regulations based on international standards do not require technical justification and cannot be challenged in the WTO under the SPS Agreement. Although governments may choose not to use international standards as the basis for their regulations, any regulations that result in a greater restriction of trade may be challenged for their technical justification.

3.1.6 Scientific basis for measures and the role of pest risk analysis

WTO Members are required by the SPS Agreement to base measures on international standards or risk assessment. The IPPC has complementary provisions stating that measures must be technically justified. Pest risk analysis or a similar evaluation based on scientific principles and evidence provide the basis for the technical justification of measures in the absence of standards or when adopting measures more restrictive than international standards. The SPS Agreement identifies certain factors that must be considered in risk assessment. The IPPC and ISPMs done under the IPPC provide additional guidance.

3.1.6.1 Consistency

Contracting parties are required to be consistent in their decisions regarding the application of

phytosanitary measures and avoid arbitrary or unjustifiable measures that lead to discrimination by ensuring that phytosanitary measures are consistent with the level of protection deemed appropriate by the contracting party. The strength of phytosanitary measures should have a rational relationship to the level of risk and similar risks should have measures of equivalent strength recognizing the practical limitations of available measures and the measure of their effectiveness.

3.1.7 Managed risk

Contracting parties should take a number of factors into account when assessing phytosanitary risks and determining their appropriate level of protection. In particular, it should be recognized that in an environment of trade and increasing international passenger movement there will always be a risk of pest introduction, and that this must be accepted. A level of protection should be decided upon as appropriate for the individual contracting party taking into account what is feasible and can be justified.

3.2 Factors affecting the application of regulations

The implementation of regulatory systems in practice is affected by international agreements, principles and standards by virtue of the actions taken (or not taken) in conformity with the government's international commitments. The principle of modification is particularly relevant in this regard. In addition, provision should be made in regulatory systems for both emergency and provisional action and the exchange of official information through IPPC contact points established by the contracting parties according to their obligation under the IPPC.

3.2.1 Modification

Contracting parties should recognize the principle of modification by incorporating designs in the structure of their regulatory systems for the review of regulations, procedures, and measures, to provide the opportunity for timely modifications based on experience, new information, or changing conditions. This includes the possibility that the NPPO may suggest to the national government that enabling authority (acts, laws, statutes) be amended to comply with international obligations or to provide a better framework for complying at the level of authority administered by the NPPO.

3.2.2 Emergency action and provisional measures

Provision of authority to take and recognize emergency action is a fundamental tenet of both the IPPC and the SPS Agreement, and is an essential element of any import regulatory system. However, emergency actions should be tempered by the need to ensure a reasonable basis for such actions. Likewise, the ability to implement provisional measures where additional information is needed or desired is a great advantage but should be used carefully as provisional measures also carry the obligation to actively pursue the information needed for a timely review.

3.2.3 Provision of information

The proper and effective implementation of the IPPC is strongly dependent on the exchange of official information. Specific obligations are identified in the Convention. Among these, phytosanitary requirements and points of entry are most frequently incorporated in regulations.

3.2.3.1 Official contact point

The establishment of an official contact point is an obligation under the IPPC and a necessary organizational component of regulatory systems to ensure the reliability and accountability of official information given and received by NPPOs.

3.3 Operational activities arising from regulations

The proper operation of import regulatory systems requires a number of activities that derive from or are affected by international agreements, principles and standards. Activities such as pest listing also satisfy requirements under the IPPC. Core operational functions such as inspection and treatment should be authorized, designed, and performed in conformity with international obligations.

3.3.1 Categorizing and listing pests

For the conduct of pest risk analyses and the formulation of regulations, contracting parties are required to have open and transparent criteria for categorizing pests and should list those pests that have been categorized, providing as necessary, the rationale and information used.

Lists include:

- lists of the pests present in their country;
- lists of regulated pests;
- lists of specified pests for phytosanitary certification purposes.

3.3.2 Provision for special imports

When required, contracting parties should be able to make special provision for the import of pests or other regulated articles for scientific research or education. Such imports are authorized subject to the possibility that adequate safeguards can be provided.

3.3.3 Designation of pest free areas, areas of low pest prevalence, and official control programmes

In the construction of regulations, contracting parties may designate pest free areas, areas of low pest prevalence, and establish or endorse official control programmes. It is necessary to make provision within regulatory systems for the processes needed to evaluate and accept such designations by other NPPOs and to respond accordingly.

3.3.4 Recognition of equivalence

Exporting contracting parties may propose alternative measures for import requirements when such measures can be demonstrated to achieve an equivalent level of protection. It is essential that import regulatory systems make provision for the acceptance, evaluation and possible approval of such proposals. Complementary procedures may be put in place using the same resources for developing proposals.

3.3.5 Provision of rationale

Contracting parties must provide the rationale for phytosanitary requirements when requested. This would usually refer to the justification provided by a pest risk analysis. Provision for adequate documentation and recordkeeping is required as well as the capability to transmit such information through an official contact point.

3.3.6 Dispute settlement

Where there are disagreements regarding the choice of import regulations or the justification for import regulations, contracting parties are expected to use various methods at their disposal to attempt to resolve differences. Import regulatory systems should anticipate the need to both initiate and respond to challenges by putting in place procedures required for official consultation.

3.3.7 Inspection

NPPOs have the responsibility for inspecting products moving in international trade and must carry out inspections promptly. Many exports of plants or plant products are perishable and if inspection is delayed they can lose value substantially. Delay in inspection may be viewed as a trade barrier subject to challenge.

3.3.8 Treatment

NPPOs have the right to treat regulated articles when necessary and appropriate. Consideration should be given to the justification for such action, any equivalent measures which may be less intrusive, and the possibility for re-export or destruction as options which may be offered to the party responsible for the consignment. Where treatments are prescribed in regulations, contracting parties must in particular be cognisant of the principles of modification and equivalence, ensuring that the regulatory system has mechanisms to accommodate and adjust for proposals of equivalent measures.

3.3.9 Non-compliance reporting

The reporting of interceptions and instances of non-compliance is necessary for exporting contracting parties to understand the basis for phytosanitary actions taken against their products on import and to facilitate corrections in export systems. Import regulatory systems need to make provision for the routine collection and transmittal of such information. Complementary systems should be established to receive, investigate and report on such notifications that may be received.

4. Components of an import regulatory system

This section describes the components of a framework for developing import regulations. It will be recognized that different levels of risk may require the use of different groups of components. Essential components include authority, technical procedures and administrative procedures.

4.1 Legal authority

The NPPO should have sole authority, by legislative or administrative means, for the stipulation of phytosanitary import requirements and the implementation of a phytosanitary import system. Therefore, an NPPO should have powers to:

- establish import conditions especially general rules of applicability, based on pest risk;
- perform inspection and testing or associated procedures, and to make the results available;
- require permits and licenses where general rules have not been established;
- impose emergency and provisional requirements when new phytosanitary situations arise pending the gathering of additional information for technical evaluation and the development of alternative entry conditions;
- make provision for special importations relating to research, education and biological control;
- negotiate bilateral agreements;
- undertake consultation or engage in dispute settlement procedures with counterpart organizations when disputes arise over import regulations;
- require a phytosanitary certificate and/or associated documentation to be presented with imported consignments;

- exchange official information with counterpart organizations;
- define criteria for, and undertake or authorize, compliance activities including powers to:
 - accredit producers or inspectors to undertake certain duties,
 - establish bilateral agreements,
 - audit and monitor systems in export countries,
 - detain, inspect, sample and test consignments on import,
 - require treatments or destruction in routine and emergency situations,
 - set fee schedules and collect monies (optional).

4.1.1 Management responsibility

The NPPO, to undertake its duties, needs a system including the following attributes:

- a management system that ensures all requirements, including appropriate legislation, scientific justification, compliance requirements, and operational and administrative activities, are satisfied;
- a person or office identified as official contact point for the import regulation system;
- the duties and authority of all personnel in the import regulatory system being described and the lines of communication between them identified and made available upon request;
- adequate personnel and resources to undertake the following functions:
 - pest risk analyses as required,
 - establishing import regulations after due consultation with domestic industry sector groups, and counterpart agencies as necessary,
 - the dissemination of information relating to import regulations to interested parties including making such information publicly available,
 - undertaking dispute resolution procedures if required,
 - establishing and auditing compliance systems at points of entry,
 - document storage and retrieval,
 - training of personnel,
 - ability to review mechanisms for the production of regulations and their implementation.

4.2 Procedures of an import regulatory system

4.2.1 Regulation construction

The construction of regulations is achieved by first conducting a technical evaluation of the product and any possible associated pests to produce a set of conditions for import, and secondly, by officially publishing, or making known to interested parties, i.e. authorizing, the conditions for import.

4.2.1.1 Technical evaluation

For any given situation, the output from consideration of technical components will consist of:

- a list of quarantine pests;
- recommendation(s) on management option(s);
- a proposed set of entry conditions.

The development of import regulations should be based on pest risk analyses. These analyses may be undertaken in a variety of ways and at different levels of complexity. This will depend on the requirements of the NPPO, on the perceived associated risks, the size of the proposed

imports, and other factors. It follows that the results may range from recommendations arising from available precedents through new, in-depth, formal analyses with a range of management options.

Existing information or experience from completed analyses may be used by NPPOs to shorten pest risk analysis procedures where possible. The nature of these outputs should be consistent with available standards. This is followed by a decision on a particular set of entry conditions.

4.2.1.2 Import authorization

After an assessment is completed and import conditions set, permission for the import, under certain conditions, needs to be stated. The import authorization process achieves this. Authorizations may be general or specific.

General authorizations are used where an authorization exists which does not require application to import, review or judgement concerning entry. This system is used for imports where generic import conditions apply. Such authorizations are provided by:

- existing regulations;
- established operating manuals or guides;
- work plans.

A specific notice, e.g. a permit, can provide specific authorization where official consent for import is noted. Cases where this type of authorization is required include:

- emergency or unique imports;
- imports with specific, individual requirements such as those with post-entry quarantine requirements;
- imports where the NPPO requires the ability to trace the material over a period of time.

The development of general authorizations is encouraged whenever similar specific authorizations become routine.

4.2.2 Dispute resolution

Where there are disagreements or disputes concerning import regulations, contracting parties are obliged to consult before using other means of dispute resolution. NPPOs should ensure that procedures exist to deal with import regulation-related problems to arrange:

- dialogue with counterpart agencies to take place when situations arise that require clarification;
- formal bilateral consultation to deal with problems or disagreements;
- third party technical consideration of technical problems (by a single expert or by experts);
- formal dispute resolution procedures involving processes such as mediation, arbitration etc. by a mutually agreed person or persons or using an organizational procedures involving consultation with the IPPC Secretariat or WTO.

4.2.3 Dissemination of regulatory information

Proposals for import regulations and completed import regulations, or aspects of them, must be made available to interested and affected parties as appropriate. These parties may include:

- producers of plants or plant products;
- importers and exporters;
- import and export industry organizations and their representatives;
- inspectors;
- other NPPOs;
- international and regional organizations;
- personnel involved in technical operations (e.g. pest management procedures).

Generally, the information made available will vary in accordance with the requirements of the groups listed. Methods may include registers, databases, Internet sites, manuals, circulars and journals. NPPOs are encouraged to make import regulatory information available by publication whenever possible using electronic or traditional means. However, in some cases, the number of interested parties is very limited so that publication for wide circulation is inappropriate.

4.2.4 Checking compliance with regulations

Compliance procedures are adopted to verify that import requirements are met and provide information on the efficacy of risk management systems for the review of regulations.

Compliance can be achieved by checking:

- documentation;
- consignment(s), by inspection or testing methods;
- procedures involved in production or treatment.

4.2.4.1 Phytosanitary documentation

Documentation can be accepted as indicating conformance with import requirements. The model phytosanitary certificates described under the IPPC are designed for this purpose.

Many NPPOs rely on the phytosanitary certificate or other documents to provide assurance of conformance with requirements. When an NPPO believes the phytosanitary certificate to be reliable and accurate, other methods of compliance checking, such as inspection or testing, can be avoided. If required, documentation can be supported by audit procedures on a random or regular basis.

4.2.4.2 Inspection and testing

There are several forms of inspection and testing systems. The most common of these is the on-arrival inspection. Specific inspections, i.e. other than general on-arrival inspections, should be described in the regulations.

The general on-arrival inspection is used in the following circumstances:

- where there are no specific requirements prior to import;
- where minimum requirements are set, e.g. phytosanitary certificate only;
- where no information is available.

Specific inspection and testing may be used in the following situations:

- on-arrival, and include:
 - specially designed inspection arrangements. These may be linked to additional controls at the point of export. Such requirements would need to be formally described.
 - inspections and testing during post-entry quarantine.
- off-shore, and include:
 - inspection during production;
 - inspection or testing at harvest;
 - inspection or testing at the point of export;
 - pre-clearance programmes.

4.2.4.3 Audit of production procedures

Where import regulations involve specific requirements concerning production procedures (usually during the growing period of the crop concerned), the requirements may include an audit of the production procedures. The arrangements for such audits are normally written into the bilateral agreement, arrangement, or work programme that describes the conditions for the import.

4.2.4.4 Supporting administrative procedures

Administrative procedures may be adopted to support compliance checking where they are required to ensure the phytosanitary integrity of the imports. These may include:

- product identification, traceability, certification checks;
- handling, storage, transport, and security arrangements;
- corrective and mitigation actions including treatments;
- enforcement arrangements, e.g. penalties;
- other administrative activities, e.g. fee collection.

4.2.5 Response to non-compliance

4.2.5.1 Non-compliance measures

To deal with cases of non-compliance with import regulations, the NPPO of an importing country needs to have non-compliance measures at its disposal. These may include:

Detention - This may be used if further information is required.

Sorting and reconfiguring - The affected products may be removed by sorting and reconfiguring the consignment.

Treatment - Used by the NPPO when an efficacious treatment is available.

Destruction - Where the NPPO considers the consignment cannot be otherwise handled, for one reason or another, the consignment may be destroyed.

Reshipment - The non-complying consignment may be removed from the country by reshipping if this is agreeable to the parties involved.

Withdrawal of regulation allowing import - In the case of repeated non-compliance, or where a particularly significant non-compliance occurs, the NPPO of the importing party may withdraw the regulation or authorization (e.g., permit) allowing import, modify that regulation or institute an emergency measure with modified entry procedures or a prohibition.

4.2.5.2 Notification of non-compliance

Where non-compliance with import regulations occurs with an import accompanied by a phytosanitary certificate, the NPPO of the importing party is obliged to notify the NPPO of the exporting party. Procedures should be in place to facilitate this information transfer.

4.3 Resources

4.3.1 Staff

NPPOs should have, or have access to, personnel who have training and experience in:

- undertaking the pest risk analyses involved in the technical evaluation;
- constructing import regulations on the basis of information derived from pest risk analyses or, if necessary, in the absence of information in emergency situations to authorize imports;
- dispute resolution procedures (or have specialist staff available);
- the distribution of information to other contracting parties as appropriate;
- dealing with all aspects of checking for compliance with phytosanitary regulations (including documentation, inspection and testing, audits, and other administrative procedures) and responding to non-compliance (including treatments and notifications).

4.3.2 Information on pests

4.3.2.1 Non-regulated pests within the importing country

An NPPO should have lists of pests, or have access to such lists, that are known to be present in the country that affect or are associated with, plants or plant products in which its country trades. These are needed in the preparation of lists of pests that are not in the country with the intention of possibly regulating such pests where this is considered necessary.

4.3.2.2 Regulated pests

An NPPO must maintain lists of all regulated pests, i.e. quarantine pests and regulated non-quarantine pests that it has categorized as regulated pests. These lists may be lists with no reference to plants or plant products, or may be comprehensive lists of pests associated with a plant, plant product, or regulated article on a worldwide basis, or may be specific lists of the pests on a crop/country basis only.

Where pest free areas are designated for certain regulated pests, information on the distribution of the pests and the measures used to maintain the PFA, should be retained by the NPPO.

With quarantine pests that are present within the country and under official control, information on the distribution and control mechanisms should be held by the NPPO.

Also, the NPPO should have data on the official control measures applied to, and the tolerances permitted for, regulated non-quarantine pests.

4.3.3 Technical information provided to NPPO personnel

NPPOs should ensure that adequate technical information is available to personnel on:

- the import regulations of the country;
- regulated pests, for crop/country combinations where possible;
- appropriate treatment procedures for regulated pests in cases of non-compliance.

4.4 Equipment

The NPPO should ensure that adequate equipment and facilities are available to carry out inspection, testing and consignment verification procedures. (See ISPM *Inspection methodology*.)

4.5 Documentation

4.5.1 Procedures

The NPPO should maintain guidance documents, procedures and work instructions as appropriate covering all aspects of the operation of the import regulatory system.

Key elements include the:

- preparation of pest lists;
- undertaking of pest risk analyses;
- inspection and testing methodology;
- treatment of non-complying consignments;
- notification of non-compliance.

4.5.2 Records

Records should be kept regarding all matters concerning import regulation.

Records of all pest risk analyses should be kept in a retrievable format in case the NPPO of a potential exporting country requests the rationale for an import regulation.

Records of imports may be kept. Where non-compliance occurs, this should be recorded so that appropriate response can be made if there is repeated non-compliance.

Sufficient recording procedures should be in place to allow the tracing of imported consignments if this is required. In the case of an outbreak of a pest or of a non-actionable occurrence, such information and procedures are essential if appropriate action is to be taken.

4.6 Communication

In order to carry out the consultative and dispute resolution processes, and the information dissemination procedures noted above, NPPOs must ensure they have timely communication procedures to contact producers and other industry representatives within their own country, NPPOs in countries that are exporting to their country, and when appropriate, RPPOs and the Secretariat of the IPPC.

4.7 Review Mechanism

4.7.1 System review

The NPPO should periodically review its import regulations and the associated compliance checking system and implement any changes to the regulations or systems if required.

4.7.2 Incident review

NPPOs need to have procedures in place to review cases of non-compliance with import regulations. Such a review may lead to the use of non-compliance responses noted in Section 4.2.5.1.

4.8 Agency Linkages

The use of administrative procedures that facilitate cooperative action, information-sharing and joint clearance activities, with relevant agencies (e.g. Customs) should be encouraged.